PSJ17 Exh 83

FENTORA 2009 Brand Plan

Content provided by:

AMFE, Clinical, HCS, Legal, Marketing, Market Research, Medical, Public Relations, Regulatory, Sales, Sales Operations, Sales Training, SciCom, and WWPP



Presentation Overview 2009 Plan

- Situation Analysis
 - Market Dynamics
 - Product Performance
 - 2009 Challenges, Unknowns & Key Assumptions
 - SWOT
- 2009 Marketing Strategy
 - Goals & Objectives
 - Marketing Strategy Overview
 - Key Strategic Imperatives with Strategies & Tactics
- Marketing Expense & Revenue Budgets
 - 2009 Marketing Budget Expense
 - 2009 Product Contribution

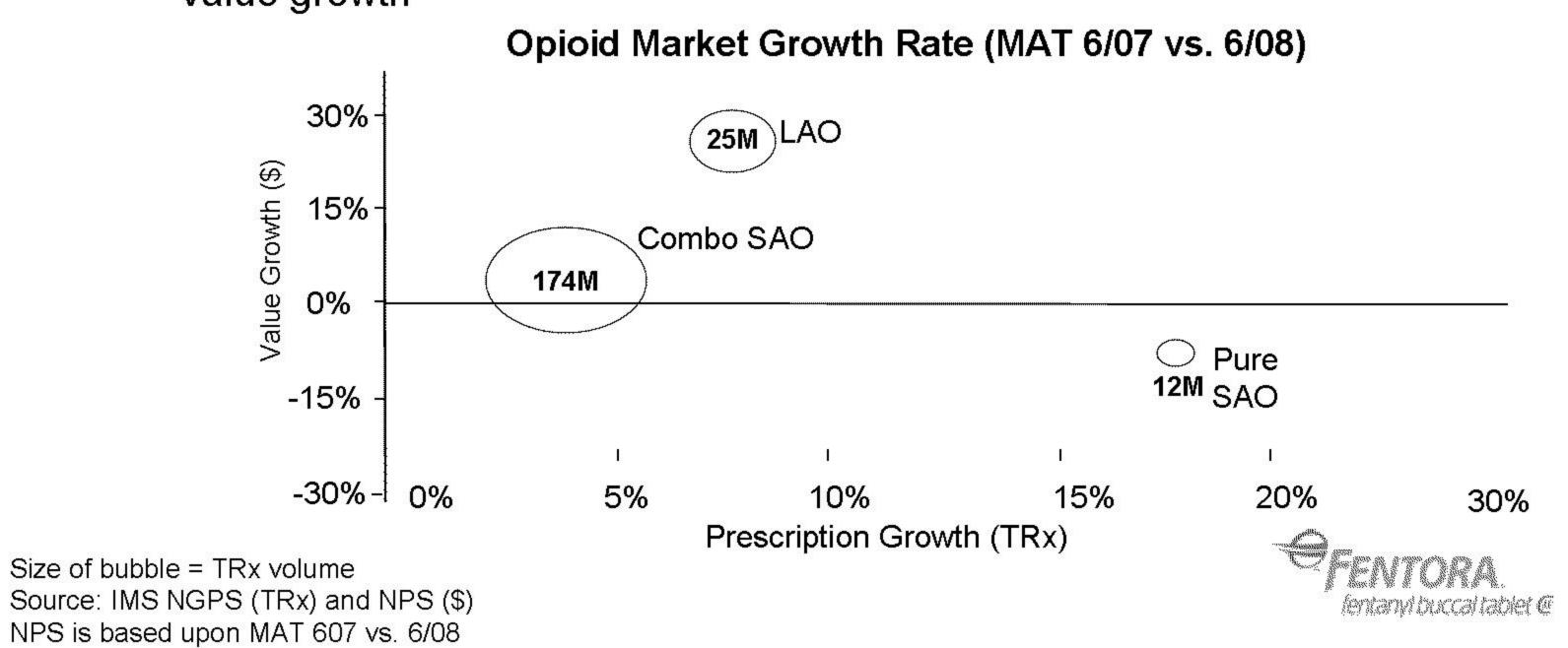


Situation Analysis

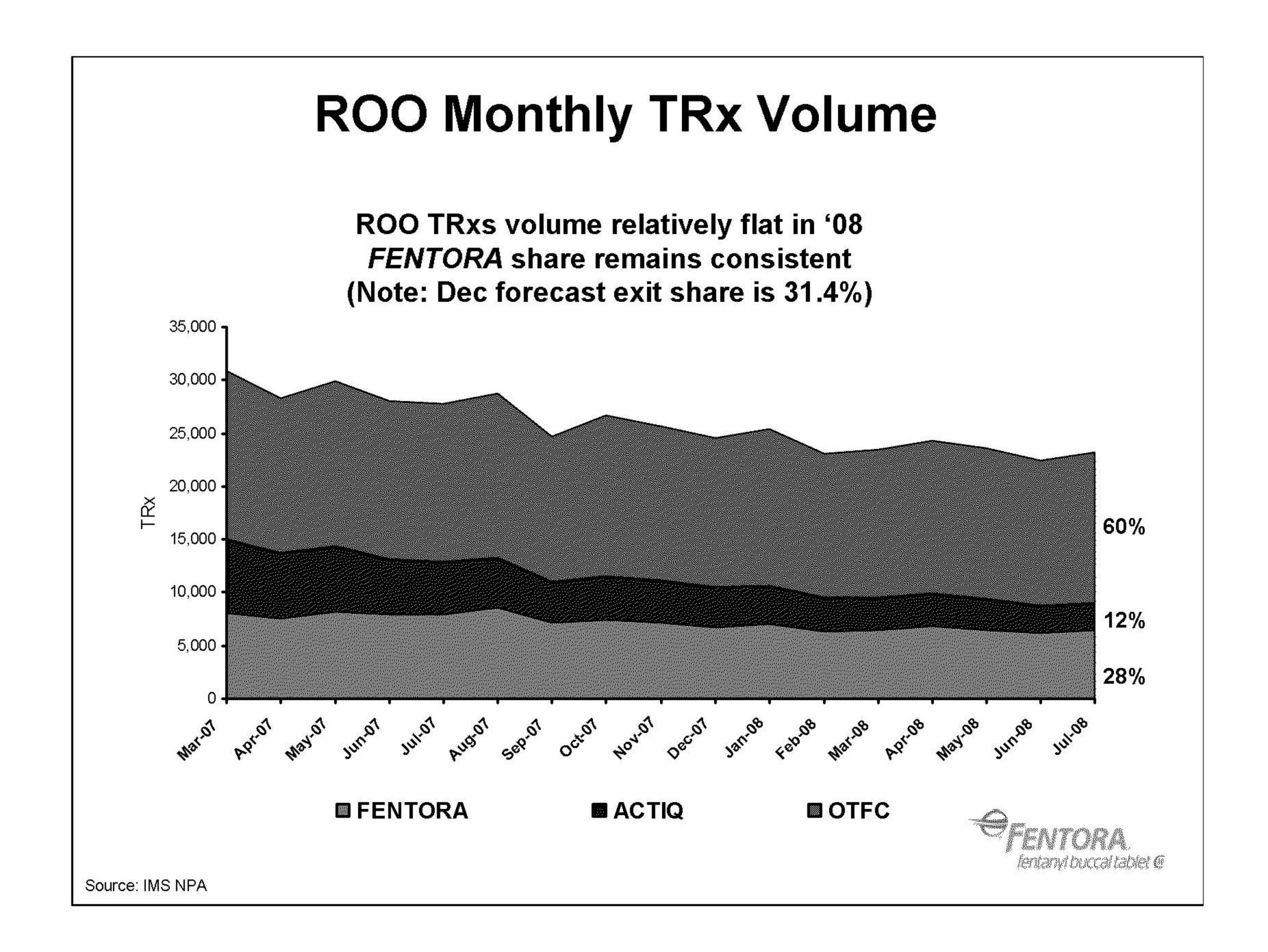


US Opioid Market

- Total opioid pain market value growth of 15% with volume growth of 5%
 - Pure SAOs (12M TRx) continue robust growth in volume, but experience negative growth in value
 - Combination SAOs (174M TRx) continue minimal growth in volume and value
 - LAOs (25M TRx) show volume growth; branded products drive strong value growth



First year LAO value declined

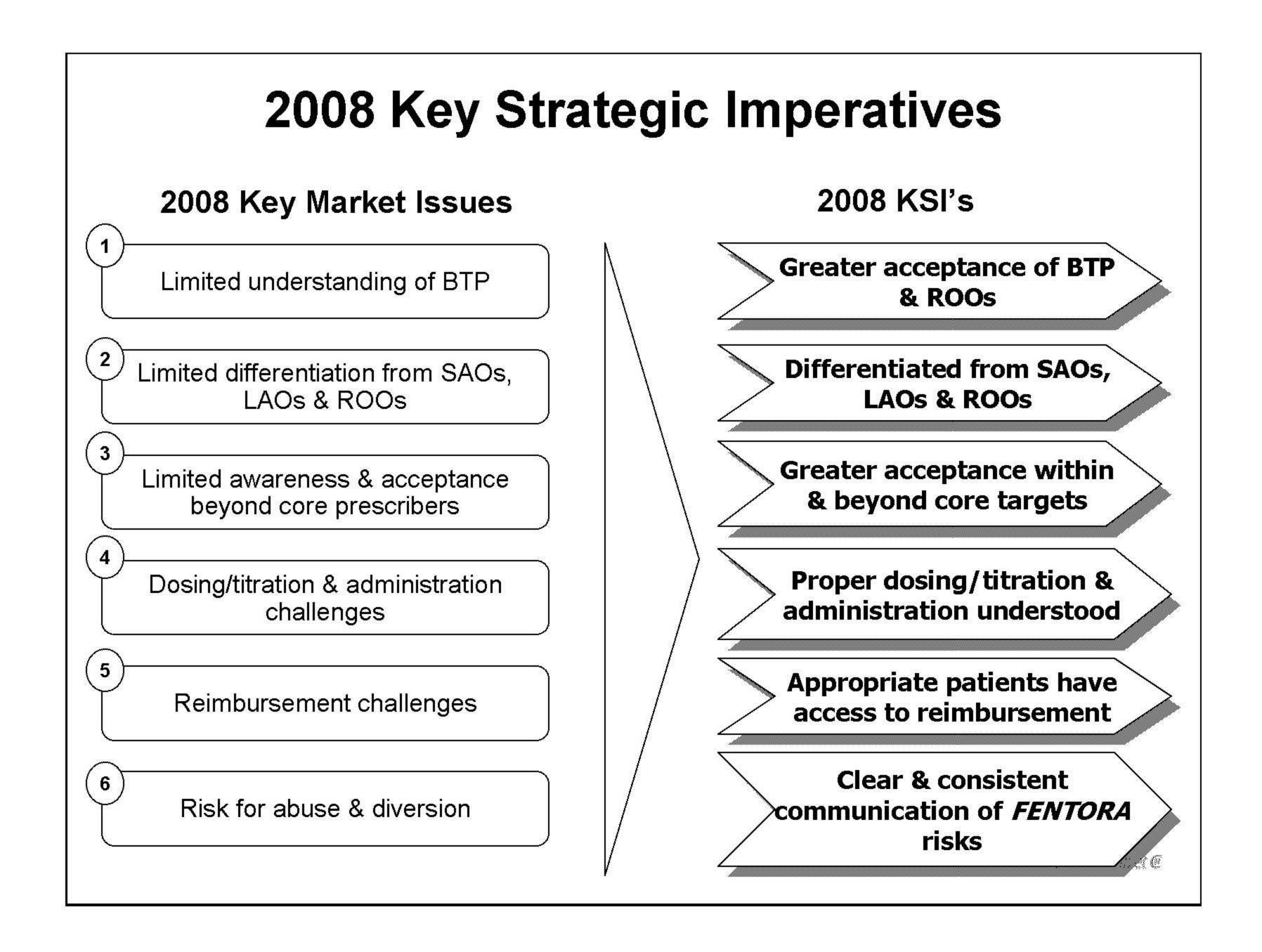


12 mos av 6i	mos avg	
Monthly average	6 mos ending 8/0	6 mos ending 2/08
Fentora	8.027	6,944
Actiq	5,704	3,756
OTFC	15,205	14,278
Total ROO 2	28,936	24,977

2008 Brief Summary

Marketing Strategy, Challenges & Budget





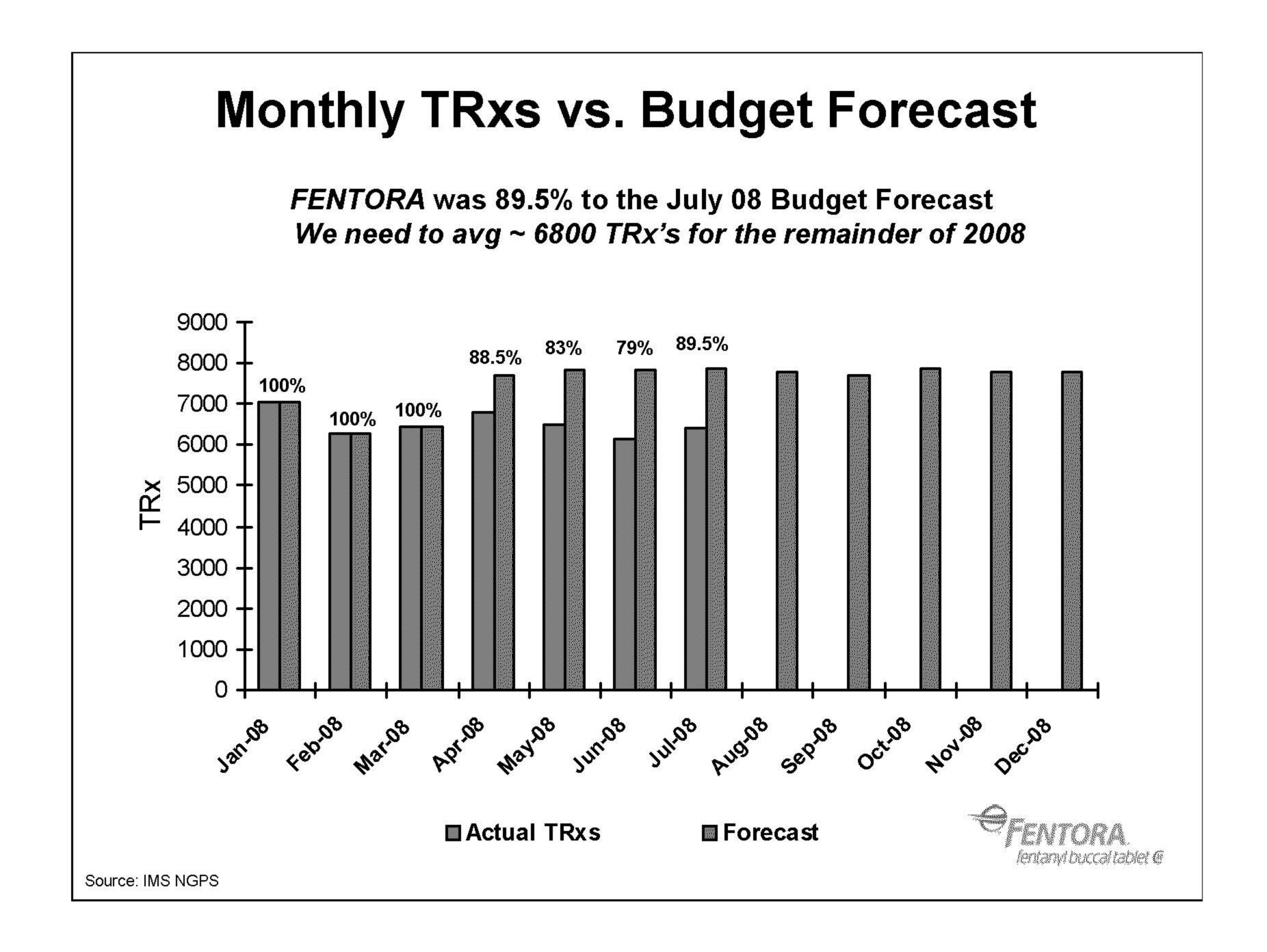
Challenges Associated with 2008 Budget

- Flat 2008 TRx trend expected with key variables not remaining constant from 2007
 - Sales force size reduced (100 → 60 reps)
 - Marketing budget reduced by 46% (\$28MM → \$15.1MM)
 - DDL/Safety communication impact still not fully realized
 - Amrix impact on ideal reach & frequency to FENTORA targets
 - IC Plan: 1H'08 = 60/40 & revised 2H'08 = 80/20
- Negative outcome from May AC & Sept CRL no expanded label limits ability to re-grow the brand
- No Differentiation vs Actiq/OTFC or Onsolis:
 - 3039 Non-approval letter received in January (no 10min onset data) fuels MHC restrictions/limitations
 - No high dose submitted, approved or launched

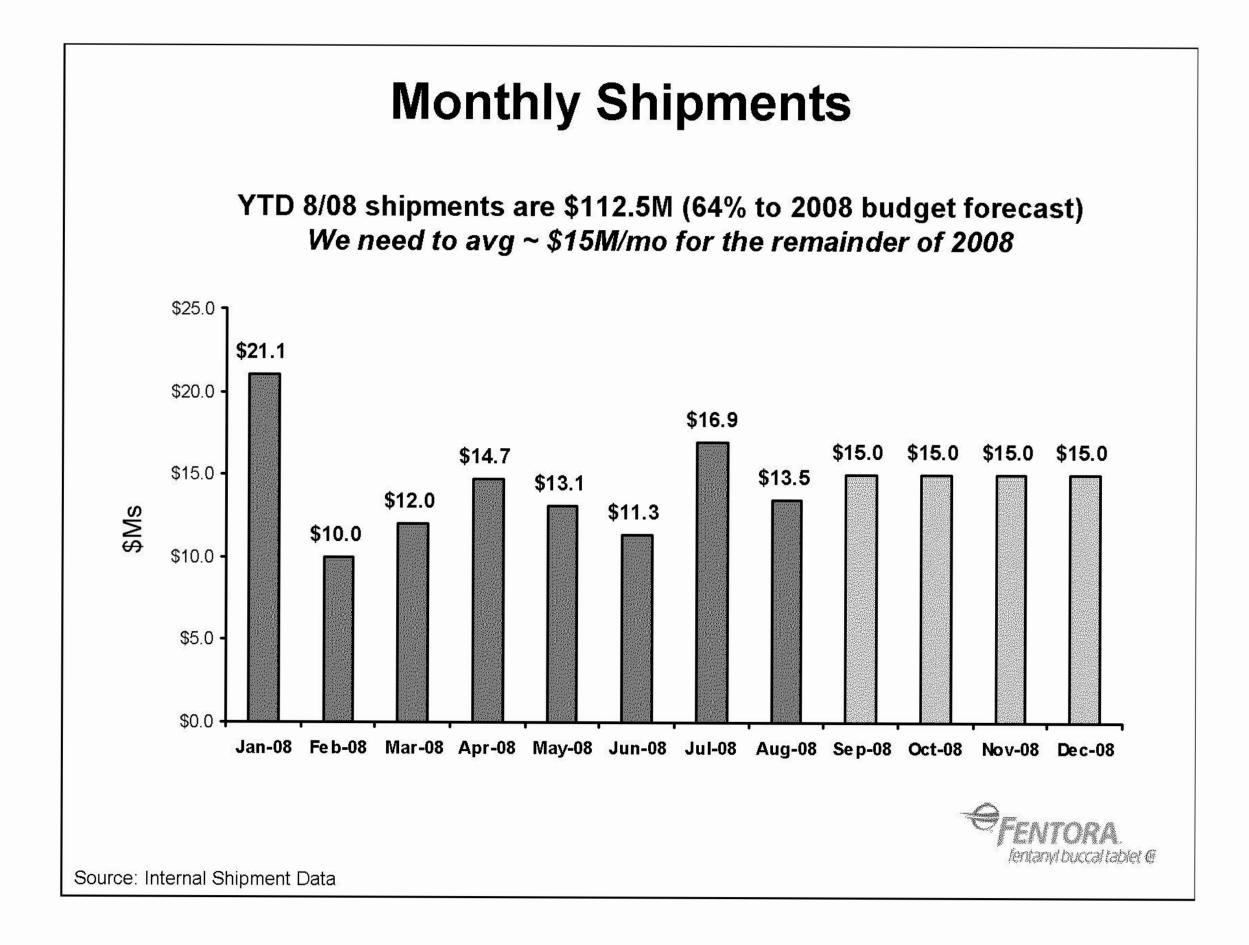


Product Performance





AUTODATE

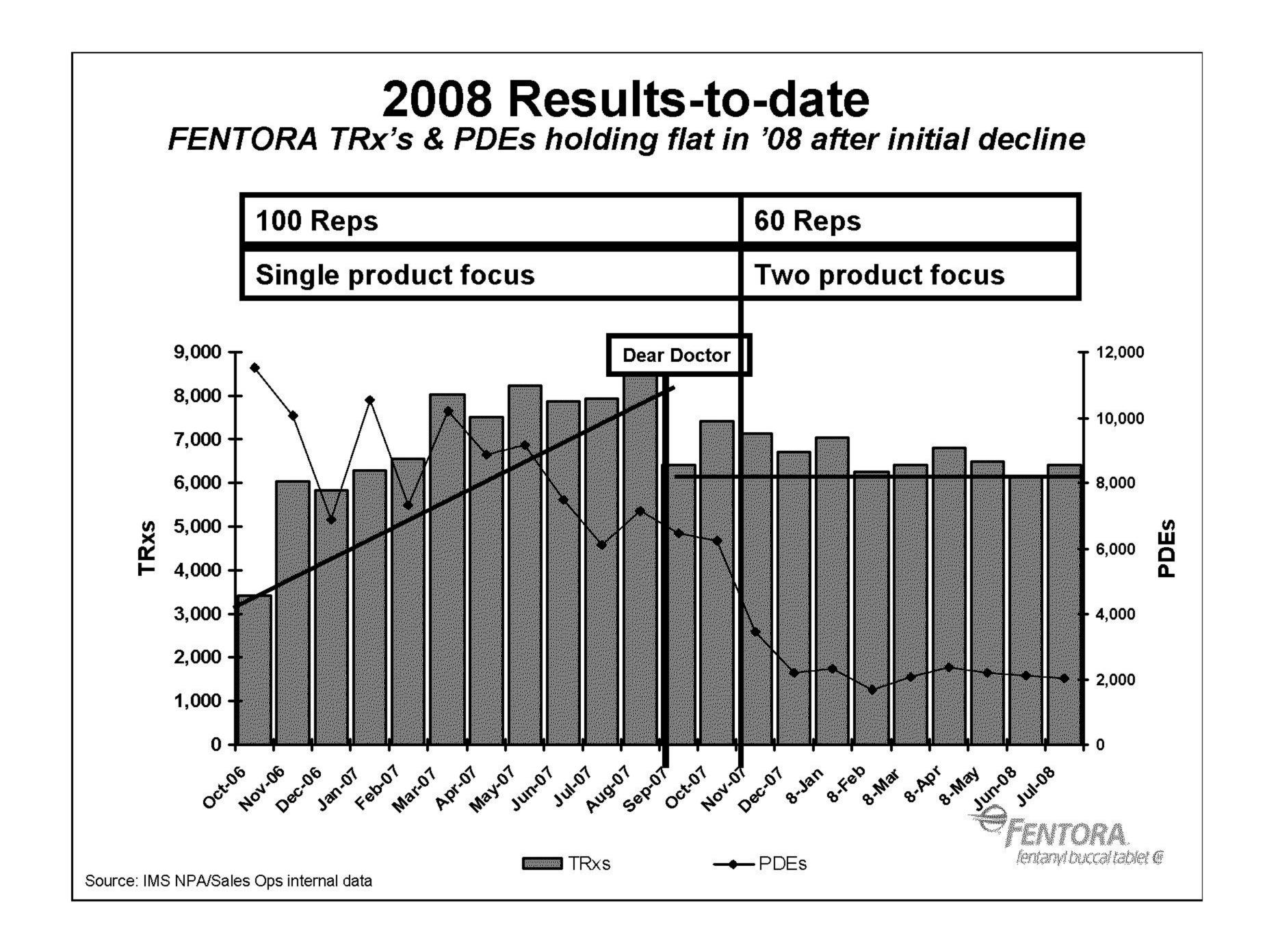


Challenges to Meeting 2008 Objectives

Prescription volume & trend impacted by the following:

- Sales force resource reductions:
 - Size 100 → 60 reps
 - Reach & frequency to FENTORA targets due to Amrix emphasis
 - IC Plan: $1H'08 = 60/40 \rightarrow 2H'08 = 80/20$
- Reduction of promotion budget '07 to '08 by 46% (\$28MM → \$15.1MM)
- DDL/Safety communication impact still being realized
- Negative outcome from May AC & Sep CRL lack of expanded label limits ability to drive growth
- No differentiation vs. Actiq/OTFC:
 - Label enhancement to include 10 min onset data not approved (Jan)
 - No high dose (plan assumption)





2008 FENTORA Expense Budget – Bare Bones

Majority of tactics designed to support 60 PCS Reps

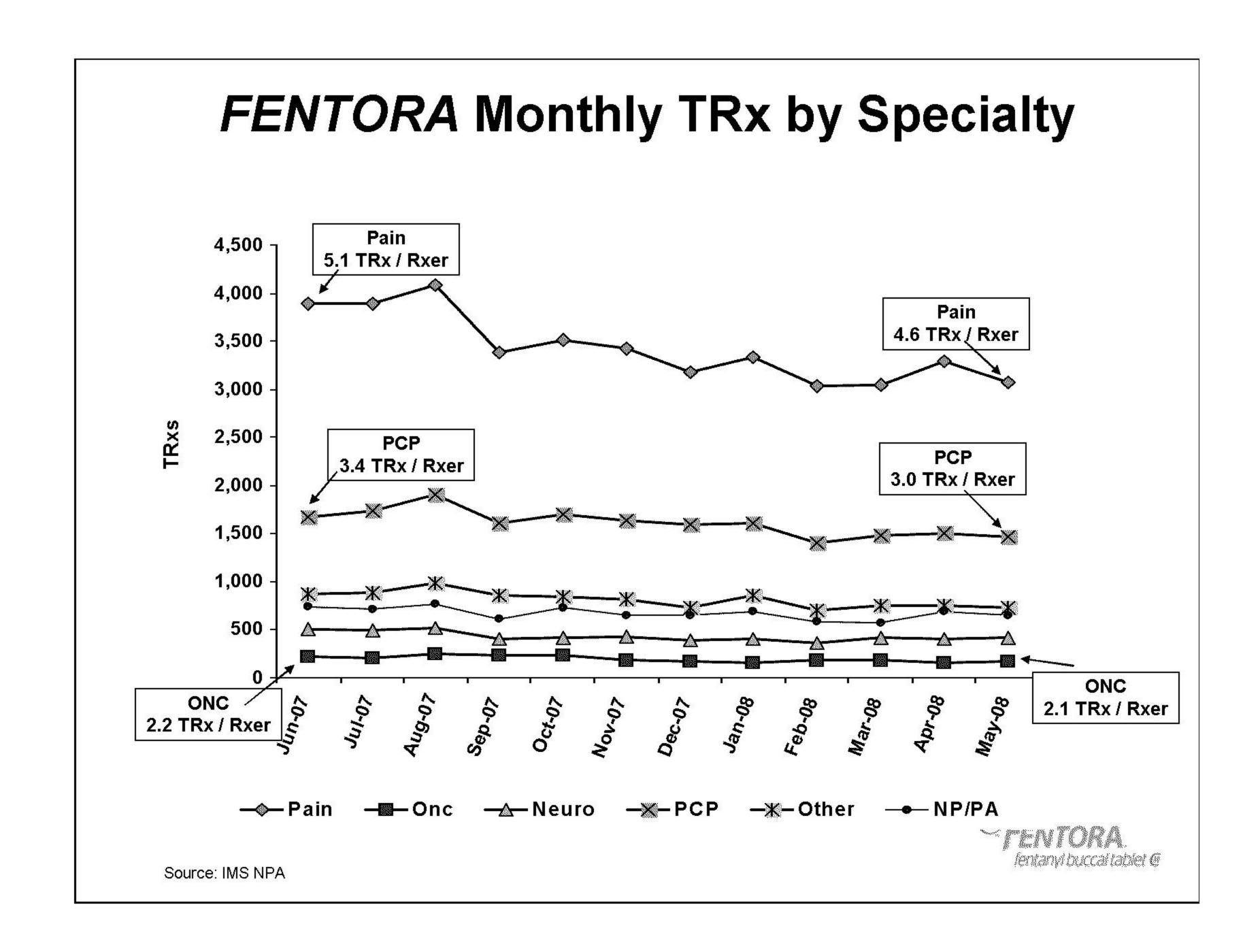
	6+6 Forecast 2008 [†]	Percent
Total Expense	\$15,175,000	
Advertising Promotional Materials	5,775,000	38%
Consultants		0%
Corporate Contributions	50,000	0%
Field Driven Speaker Programs	2,700,000	18%
Market Research	1,100,000	7%
Marketing Promotional Programs	0	0%
Medical Education	1,800,000	12%
Meetings, Conf, Congresses, Conv, Exhibits	1,300,000	9%
Miscellaneous Operating Expense	0	0%
Public Relations	1,000,000	7%
Reprints	250,000	2%
Risk Management*	0	0%
Samples & Debit Card Program	1,200,000	8%

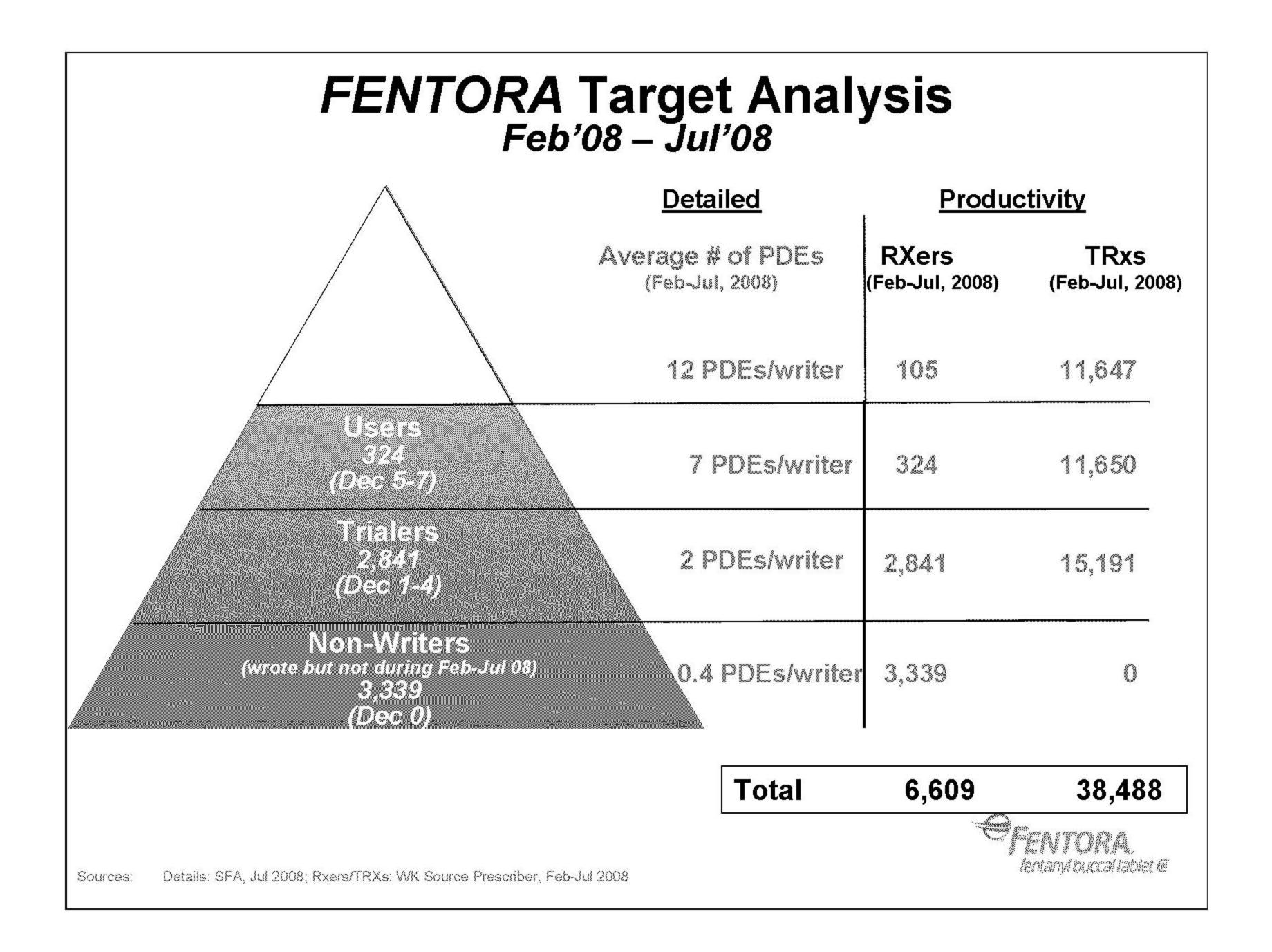
[†]Original 2008 Marketing Budget = \$18.5M → shifted \$3.4M to Amrix Marketing

Core Tactics

- Impact Personal Selling within Core Targets
 - Revised brand campaign mats
 - CSPs (FENTORA & A/A/D)
- Revised Promotional Materials based on label change and 3039 Non-approval letter
- Non-Personal Selling Support
 - Media & journal tactics
 - E-Marketing initiatives
- Revised Sample Voucher Program
- Abuse, Addiction & Diversion Speaker Training
- Managed Care Initiatives
 Pilot Practice Manager Program
 & debit card program
- Increase in PR & Market Research spend due to Advisory Comm needs & conjoint analysis

^{*} Assumes Regulatory will cover RMP expenses





We have nice activity from our cores

What are we doing from a productivity standpoint

Non targets or FIT's may or may not have been called on but they have Rx'ed

Ask questions- what's going on?

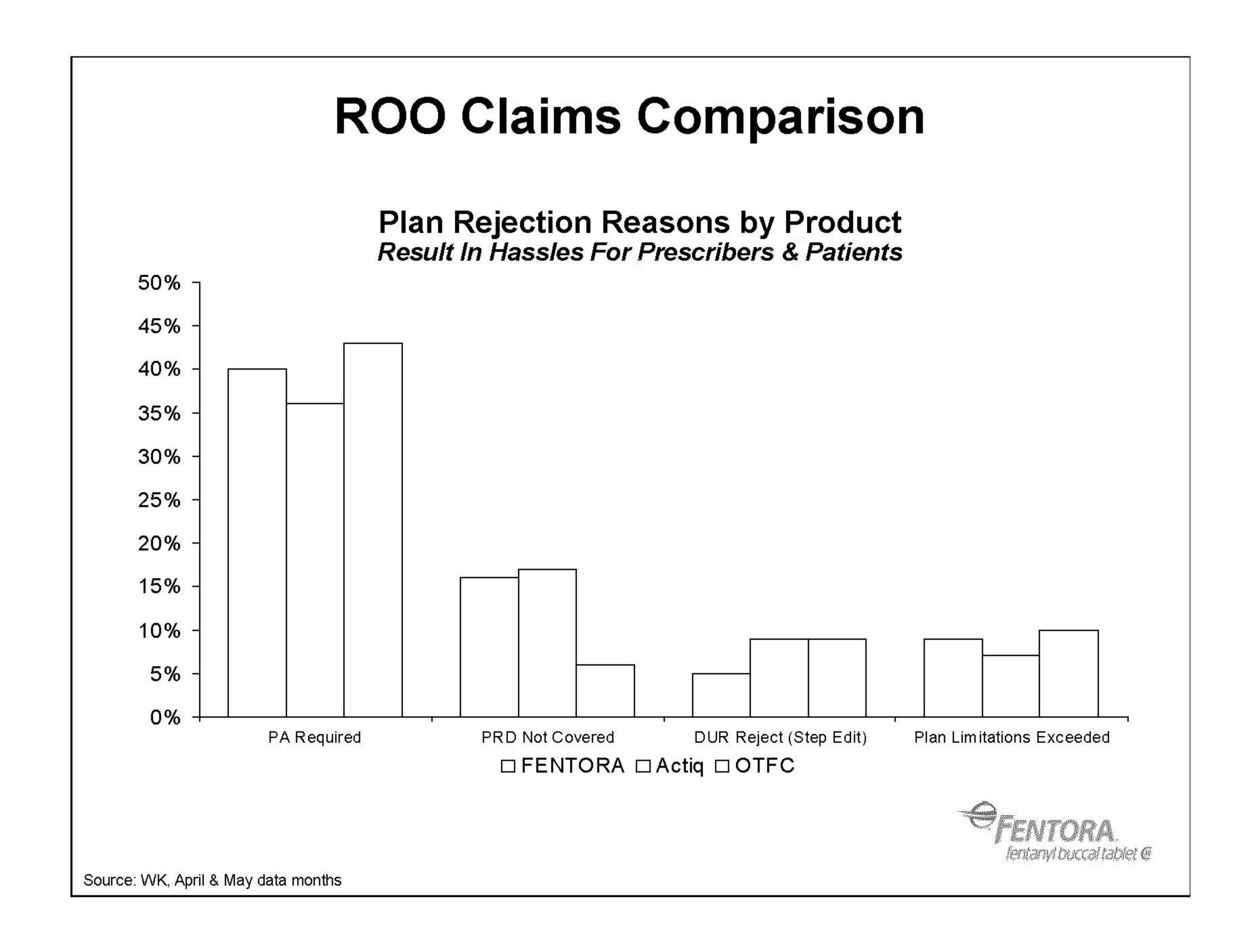
In comparison to June data

Core- Rx went down slightly and TRxs increased (June was 1252 Rxs with 29,788 TRxs)

High Opioid- increased from 89 Rxs and 571 TRx's in June

Low Actiq- increased to 832 from 777 Rxs and 5148 TRxs from 42,96

And for non-targets/FIT's increase to 1381 from 1128Rxs and 10,787 TRxs from 7,687



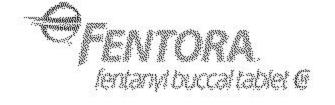
2009

Challenges, Unknowns & Key Assumptions



2009 Challenges

- REMS/Registry logistics
- New competitors
 - 3rd generic OTFC (Sandoz 1H09)
 - Onsolis (BEMA fentanyl 1H09)
- Lack of differentiation/inferiority to current ROOs
- Reimbursement hurdles
- Limited resources
 - SF size vs Meda
 - Promotional spend
- Concerns for abuse, misuse & diversion



Key Unknowns Risk/Opportunity Analysis

Area Risk/Opportunity	Timing	Probability (VH/High/ Med/Low/ VL)	Impact (VH/High/ Med/Low/ VL)	Potential Effect on Sales	Potential Effect on Contribution
REMS (timing/requirements impact) Ris	sk 1H09	VH	VH	\rightarrow	\downarrow
SECURE Registry - FENTORA Ri	sk 2Q09	VH	VH	\rightarrow	↓
New competitors: Ris •Onsolis launch •3rd OTFC	1H09	High	High	\	↓
Potential Registry – other ROOs Ris	sk 1H09?	Med	VH	↓ ↑	↓ ↑
Increase in Sales Resource Op	pt 1Q09	High	High	↑	
Expanded Label Op	pt 1Q10	High	VH	↑	↑
New administration, Optitration & dosing options (sublingual & high dose)	. I Z@09 →	High	High	↑	↑
Additional Market Noise for BTP O	pt 1H09	High	Low	↑	1

Strategic

Stakeholders

- Shareholder
- Business Partner
- > Customer
- > Vendor
- ➤ Health Care Providers

Market Dynamics

- > Competition
- ➤ Economic Factors
- Demographics
- ➤ Globalization
- Brand Protection
- Gray Markets
- ➤ Government Price Controls/Parallel Trade
- Medicare/Medicaid

Planning & Resource Allocations

- > Organizational Structure
- Strategic Planning
- Customer-Centered Product Flow
- ➤ Lifecycle Portfolio Assessment
- > Annual Budgeting
- > Research Investment
- > Forecasting
- ➤ IT Infrastructure/Capability
- Charitable Giving/Philanthropic Activities

Communications

- > Employees
- ➤ Media
- Public Relations
- > Investors
- Records Retention

Operations

- People ➤ Culture/Leader Behaviors
 - Recruiting & Retention
 - > Development & Performance
 - ➤ Health & Safety

Research

- ➤ Clinical Trials/cGCP
- Phase IV Studies
- ➤ Toxicology/cGLP
- ➤ Development/cGMP
- ➤ Medical affairs/cGCP
- > Animal Rights

Global Supply Chain

- Sourcing
- ➤ Production & Manufacturing (cGMP)
- Product Availability
- > Supply Chain & Logistics
- Distribution
- Regulatory Conformance and Change

Sales & Marketing

- > Commercialization
- ➤ Marketing & Advertising
- ➤ Licensing & Royalties
- Product Sales & Pricing
- > Customer Support

Business Continuity

- ➤ Plant Security & Alternative Sourcing
- ➤ IT Security/Access/Backup
- Research Stability
- Product Integrity

Compliance

- Governance

 ➤ Board Performance
 - Tone at the Top
 - Corporate Monitoring
 - Corporate Social Responsibility

Code of Conduct

- > Ethics
- > Fraud

Legal & Regulatory

- > Trade/Customs
- > Employment Issues
- Securities
- Environment
- PrivacyPharmacovigilance
- > Contract
- Contrac
- ➤ Liability
- > Healthcare
- FDA/USDA/EMEA

Financial/Reporting

Market

- ➤ Interest Rate
- Foreign Currency
- > Commodity
- Derivatives

Liquidity & Credit

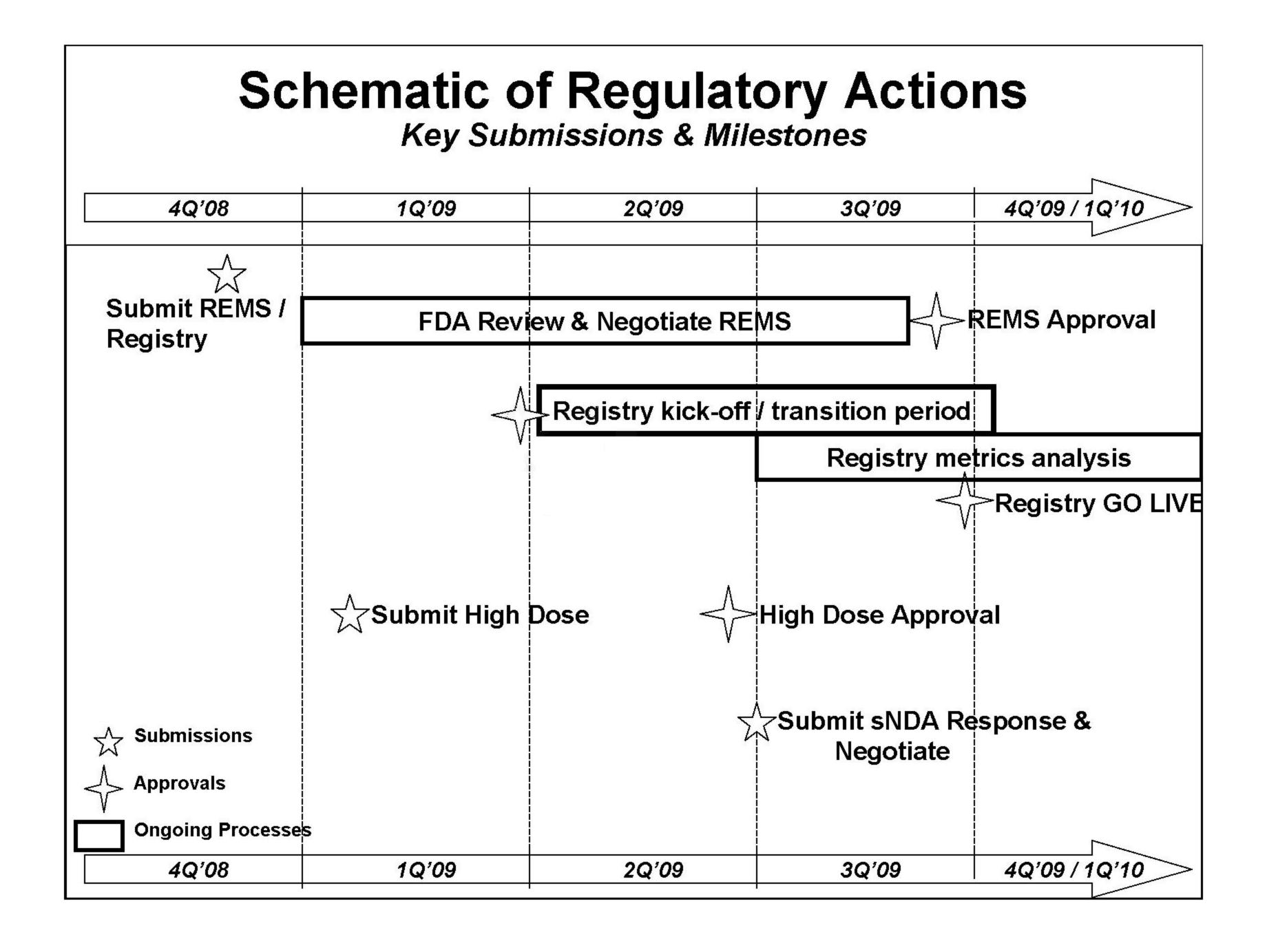
- > Cash Management
- > Funding
- Hedging
- Credit & CollectiblesInsurance
- > Insurance

Accounting & Reporting ➤ Reporting & Disclosure

- ➤ Internal Control/SO 404/302
- > Tax
- Transfer Pricing

Capital Structure

- > Debt
- > Equity
- > M&A
- > Pension Funds
- Stock Options



2009 Key Assumptions

Registry	Registry enrollment targets (~6000 HCPs): • Core prescribers deciles 3-10
ixegistry	Deciles 0-2 + other skilled opioid Rx'ers
	60 → 110 PCS Representatives – January
Sales Force Expansion	Create attractive IC plan
	New competitors 1H09:
Competition	Onsolis
	3rd OTFC
	 3rd OTFC Sublingual administration secured (1H09)
Dogulatom, Astions	
Regulatory Actions	Sublingual administration secured (1H09)



Registry Program Assessment



Postmarketing Safety Use in Opioid Non-Tolerant Patients

Based on limited data sources ~20–40% of patients currently on FENTORA Do not meet the strict definition of opioid tolerance in the label

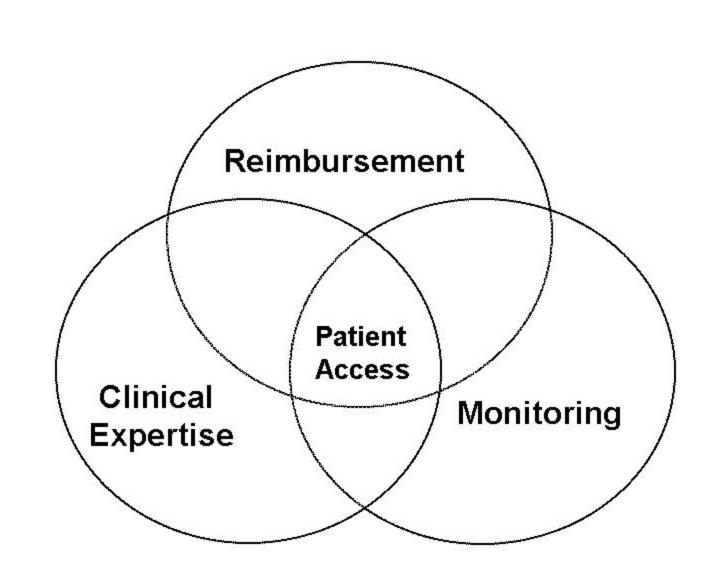
Data source and methodology	< 60 mg/day morphine eq.	≥ 60 mg/day morphine eq.
Spontaneous postmarketing reports ^a	14% (208/1497)	86% (1289/1497)
IMS prescription claims database ^b	23%	77%
Verispan with IMS methodology ^b	25%	75%
	No pain product	Any pain product
Verispan VOCON concurrency analysis ^b	41%	59%

^a Cumulative through Dec 31, 2007 (n = 1989).

^b 2007.

Structuring a Registry

- Development:
 - Internal:
 - Cross-functional input & ownership of components are critical to insure objectives are achievable and are met
 - Dedicated in-house staff needed to manage registry (in Medically-related function not Sales & Marketing)
 - External:
 - Advisors are invaluable
 - Periodic meetings with participating physicians
- Design:
 - Effective & efficient process to ensure patient access
 - Simple to understand & follow enrollment process
 - Ability to provide reimbursement support
 - Processes must protect patient privacy
 - Ability to utilize the data for both safety & other medically relevant metrics





Excerpts from 2007 presentation Boston Bio Conference: Global Registries: The Genzyme Experience

Market Situation Overview: Competitive Analysis



Let's know take a look at our competitive climate and what are some of the products that will be coming out soon.

FENTORACompetitive Profile Comparison

Key Attributes	EENTORA Buccal Tablet	Onsolis Bulgal Disc monte management
Indication	BTP in CA pts (99-14) (Pursuing BTP in non-CA patients)	BTP in CA pts (Pursuing BTP in non-CA patients)
Onset	15 min	15 min
Duration	60 min	60 min
Absolute Bioavailability	65%	70%
Dosage	100 - 800 mcg	200 - 1200 mcg
Safety	Comparable	Comparable
Mucosal Irritation	Low	Minimal/none
Taste	"Baking soda"	Mint
Sales Force Size	110 PCS 2 product calls	Total: 465 PCP: 388 Specialty: 77 Primary position expected
Targets	Registry participants ~6000	Potentially 30K skilled opioid prescribers

Source: BioDelivery Science International April 25, 2007; Press release Onsolis™ Fentanyl Demonstrates Substantial Transmucosal Delivery in Absolute

Bioavailability Study; Press release May 14, 2007 BDSI Announces Positive Key Secondary Endpoint Results for Onsolis™ Fentanyl; Press release December

17, 2007 Endo Announces Positive Results From Interim Analysis of RAPINYL™ Phase III Clinical Trial; Lennernaes B et al. Br J Clin Pharm. 2005;59(2):249-253. Abstral Swedish PI July 2008.

SWOT

Strengths

- Highly efficacious
- Onset 15 min
- Multiple & convenient routes of administration
- Breadth of clinical data
- Active clinical program
- Patent to 2019

<u>Weaknesses</u>

- Registry System
- Premium price
- MCO reimbursement hurdles
- Limited differentiation from SAOs & other ROOs
- Eroded relationships with HCPs
- Highest dose only 800 mcg
- Fast onset perceived as a safety concern

Opportunities

- Increased noise by new market entries will raise awareness of BTP
- CNCA Treatment guidelines in development by APS/AAPM
- Increasing patient population
 - Aging
 - Increasing cancer survival rates

Threats

- Limited BTP and ROO awareness
- Miscommunication between HCPs and patients regarding BTP
- Increasing MCO hurdles on premium priced products
- Shrinking ROO market
- New competitors: 3rd OTFC & Onsolis
- Safety concerns for abuse and diversion



Marketing Strategy



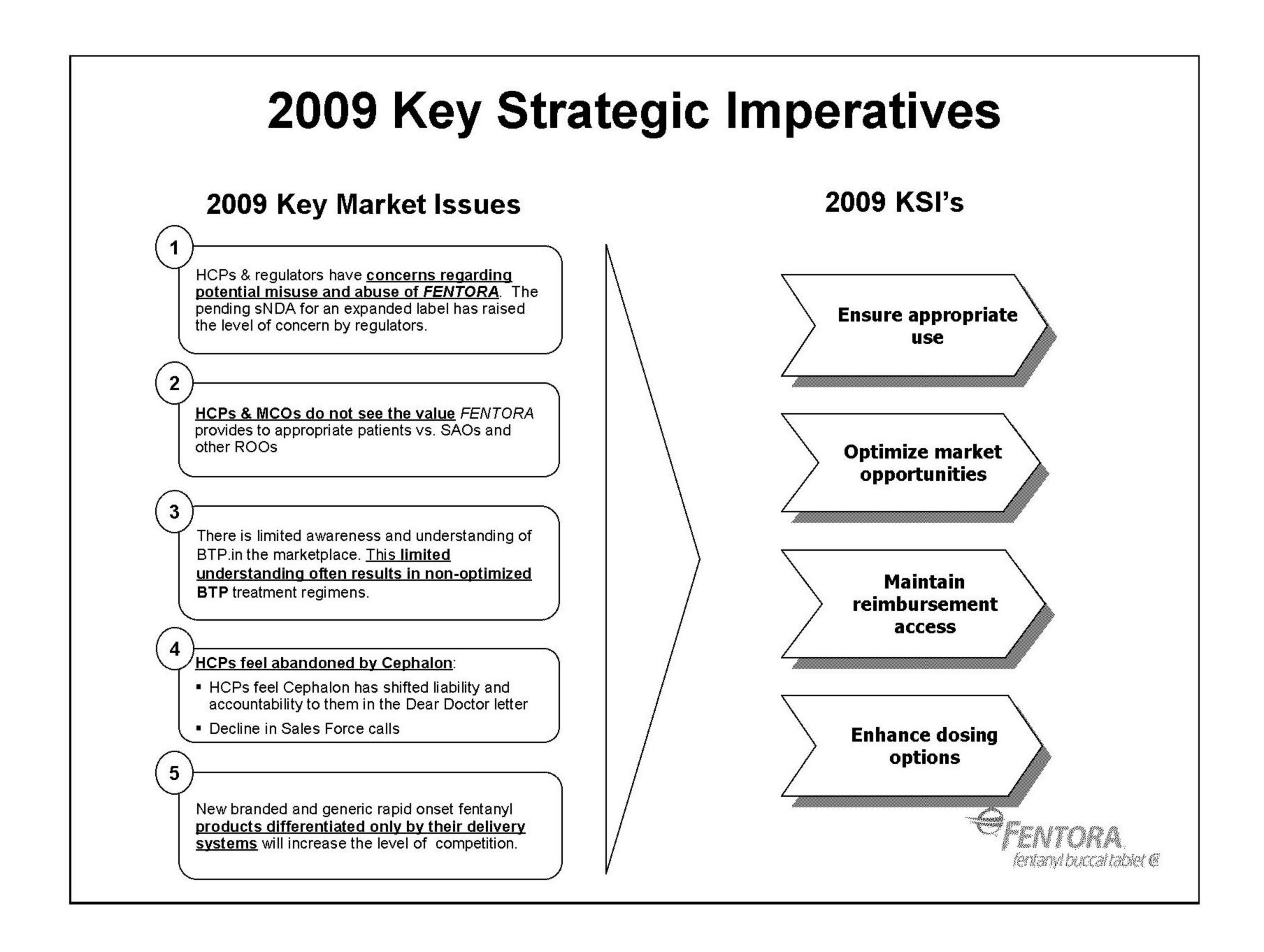
2009 Goals

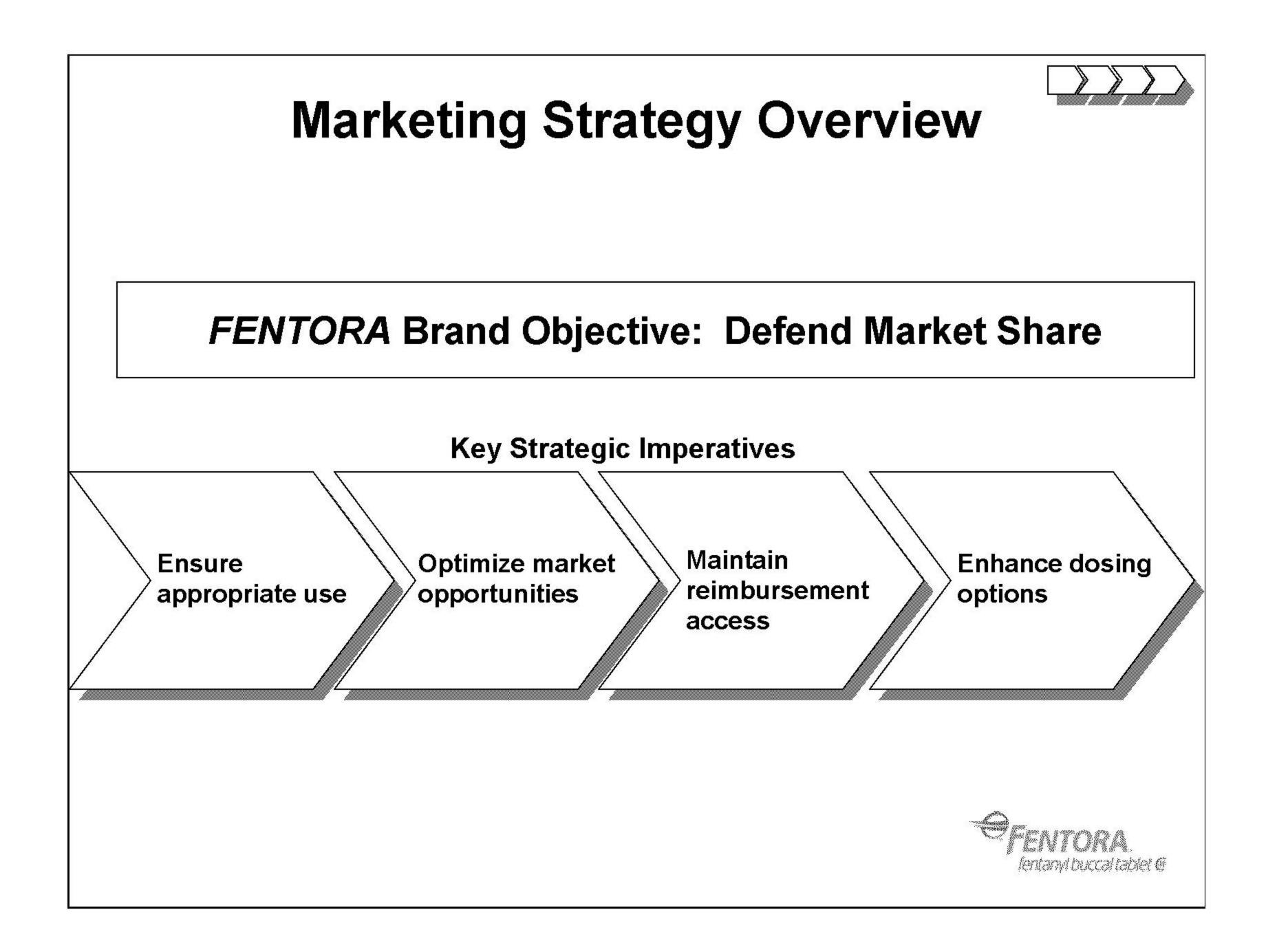
\$175M Total Revenue 76,334 TRx's 29.7% TRx Exit Share

Assumptions

- Efficient and effective registry roll out
- FENTORA prescribing will mostly come from
 - Registered core prescribers (Deciles 3-10)
 - Incremental use by other registered prescribers (Deciles 0-2 + high opioid)
- Potential price increase
- 110 PCS Representatives
- \$20M Marketing budget



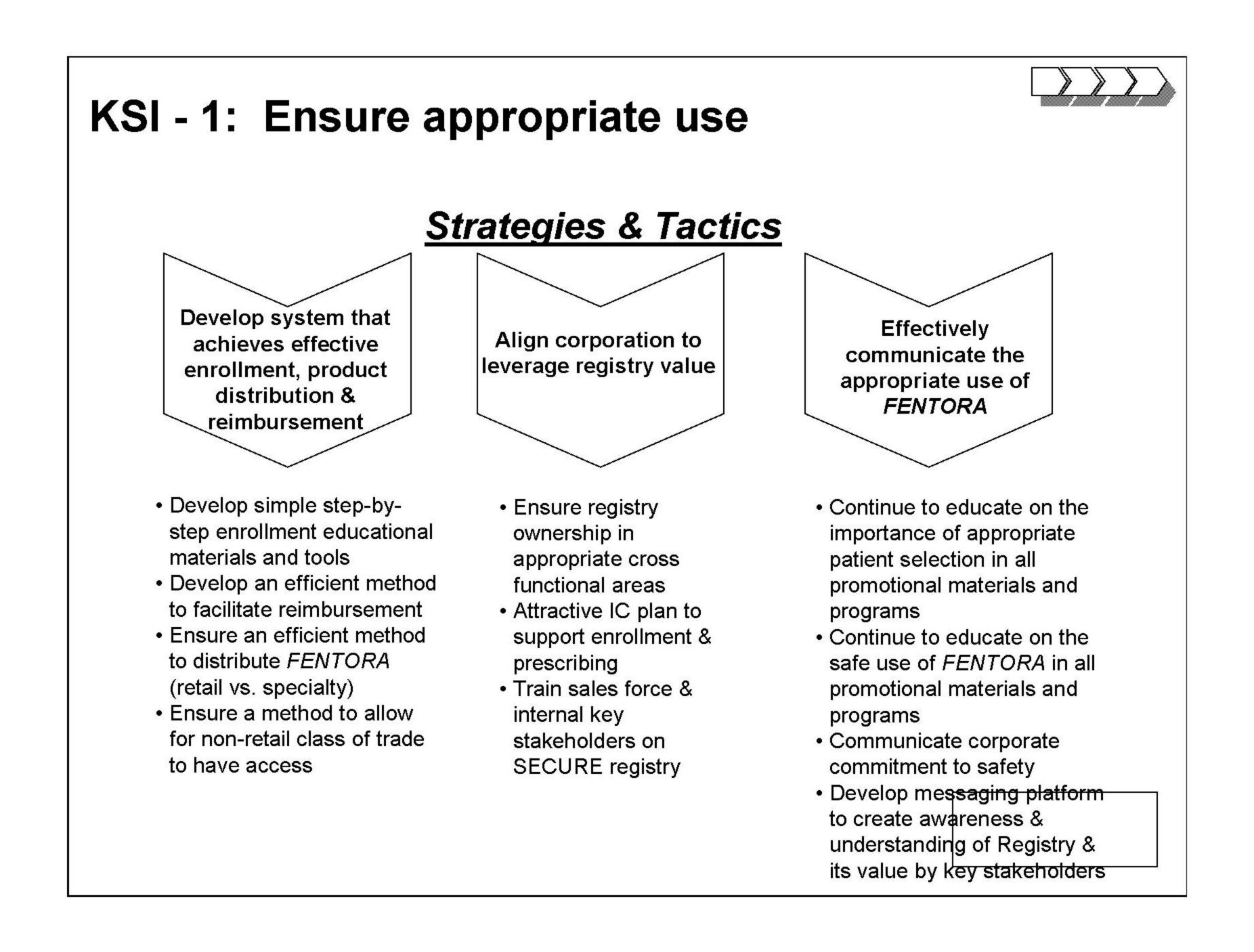




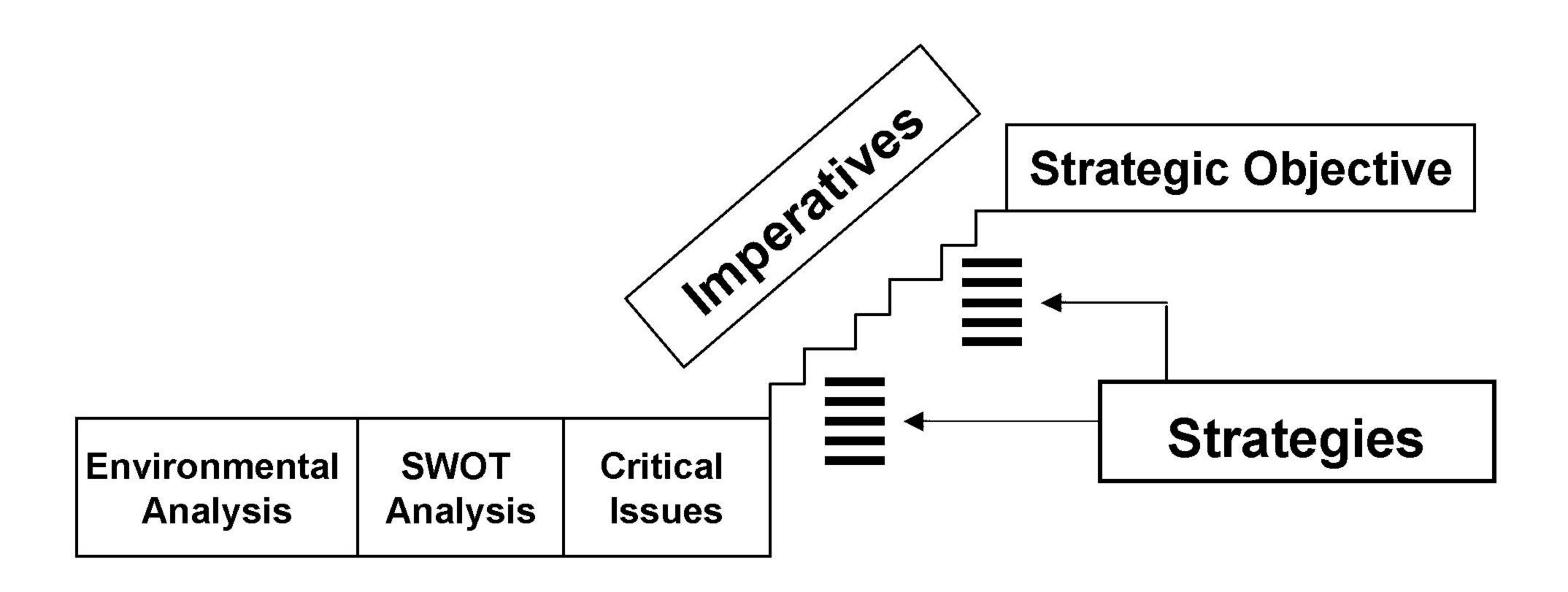
Taken from the <u>Business Strategy</u> slide later in this deck, please list in the "Business Strategy" field above:

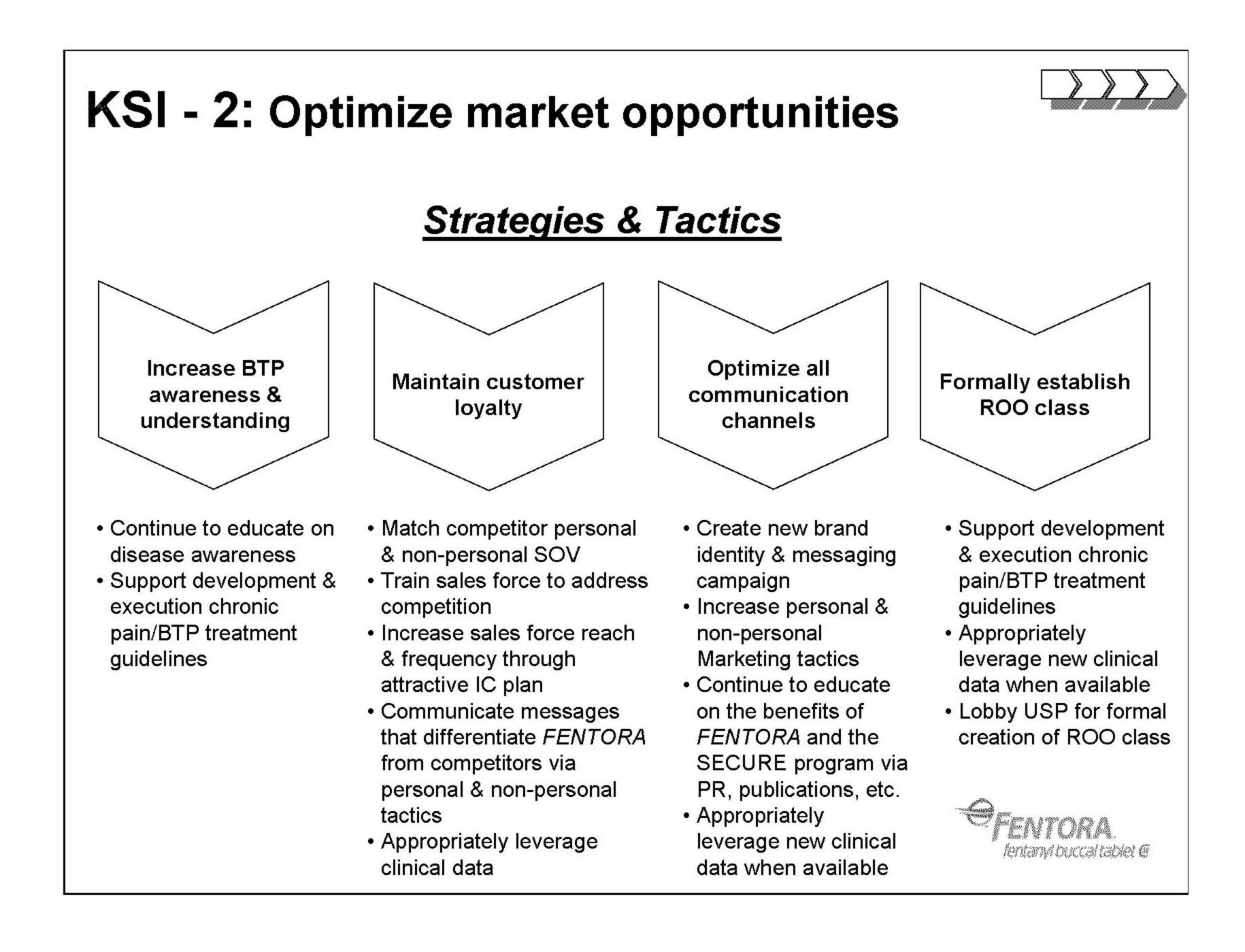
- Most important indication
- Key Target Audience
- Basic Approach to the Marketplace

Taken from the <u>Strategic Imperatives</u> slide later in this deck, please list each Imperative in the fields provided.

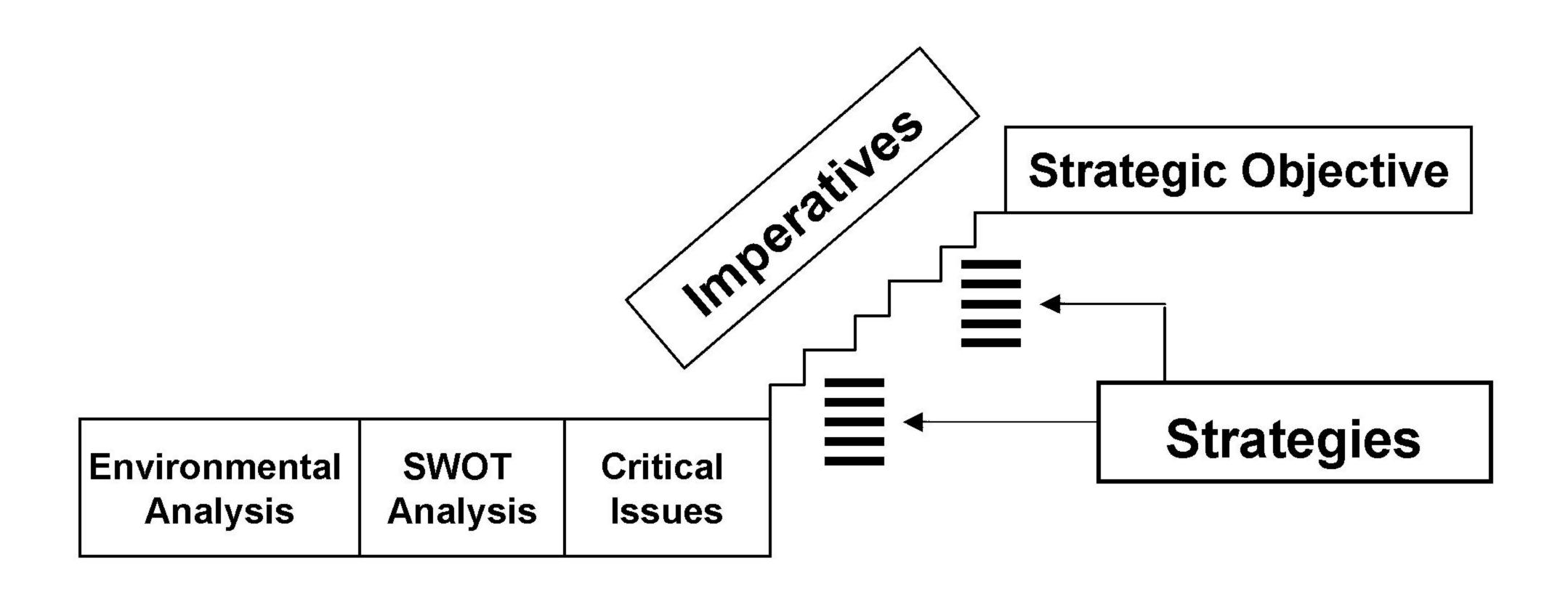


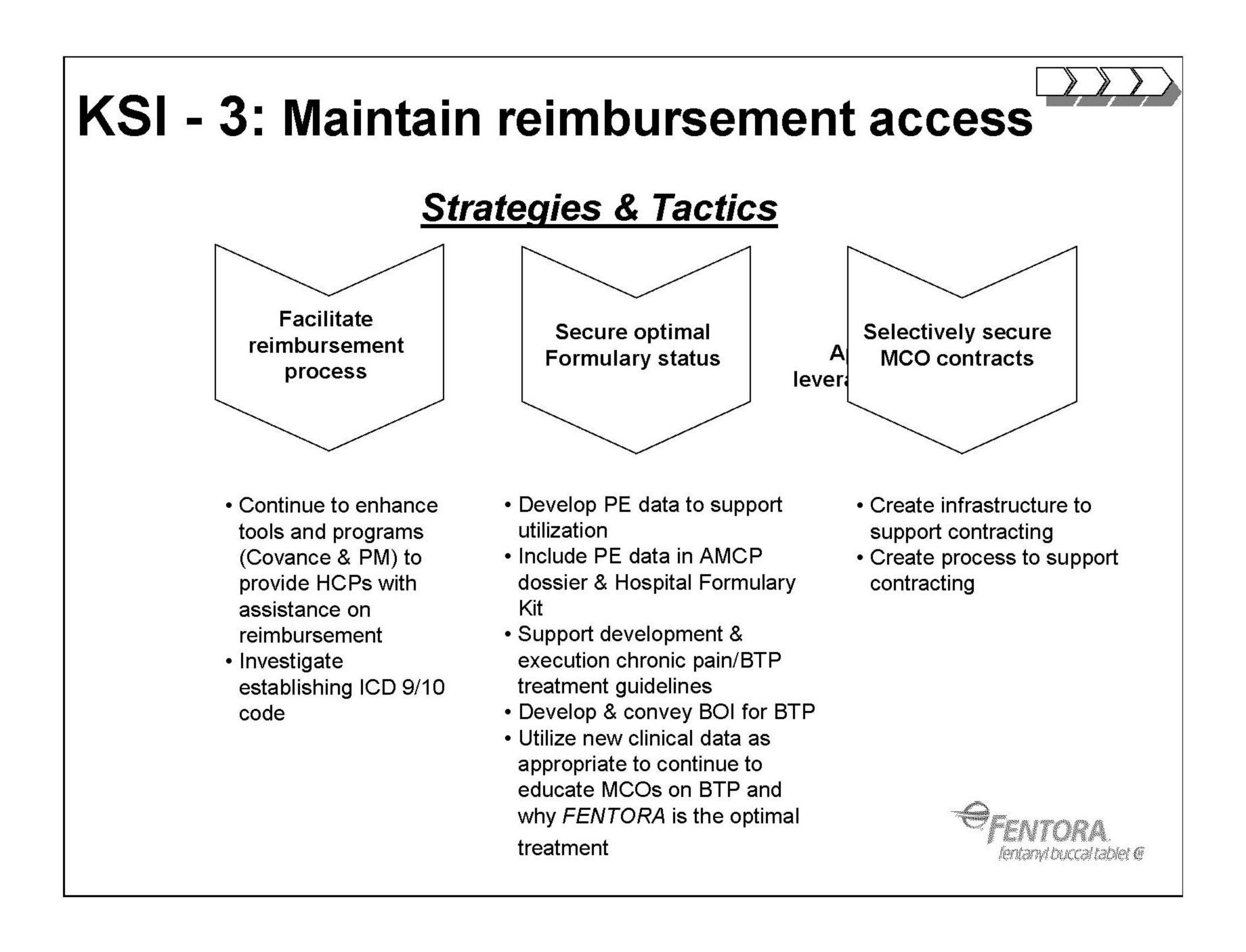
- Key strategic actions to support the "Strategic Imperatives"
- Sub strategies can be included when necessary
- List assumptions key to success of the strategies
- Describe any Action Plans that you feel senior management must be made aware of



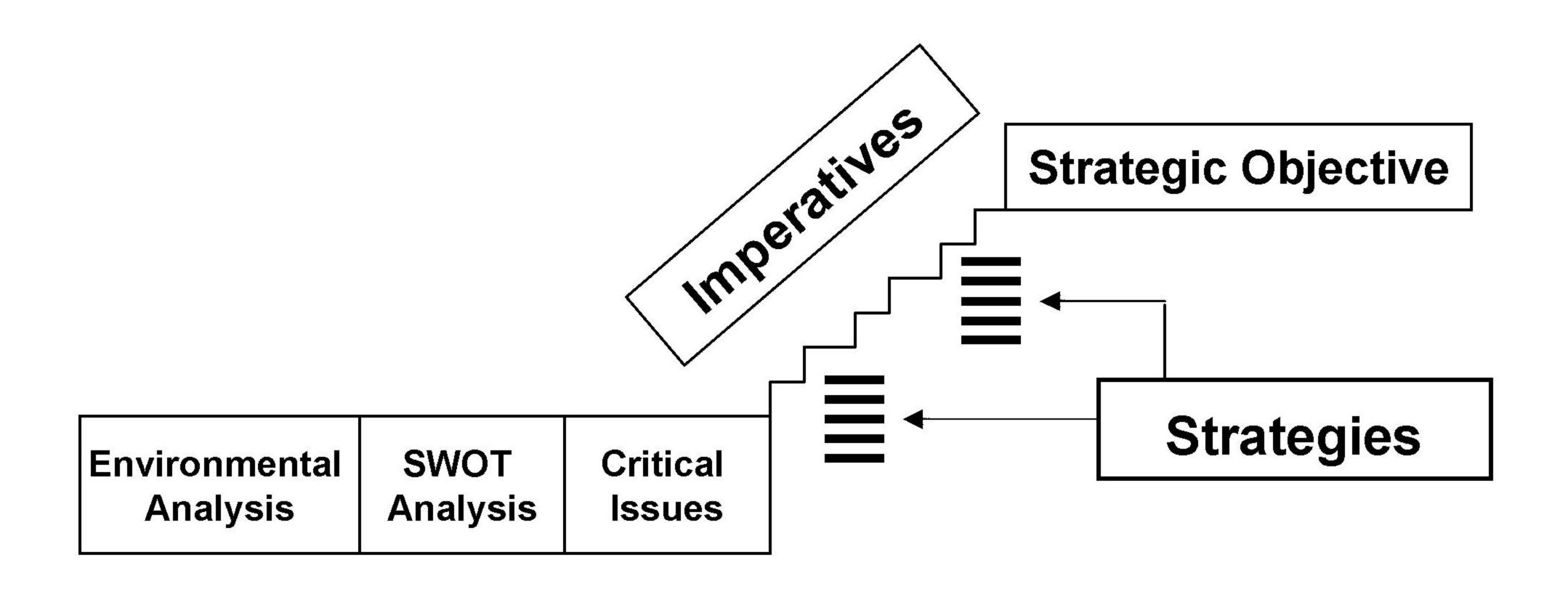


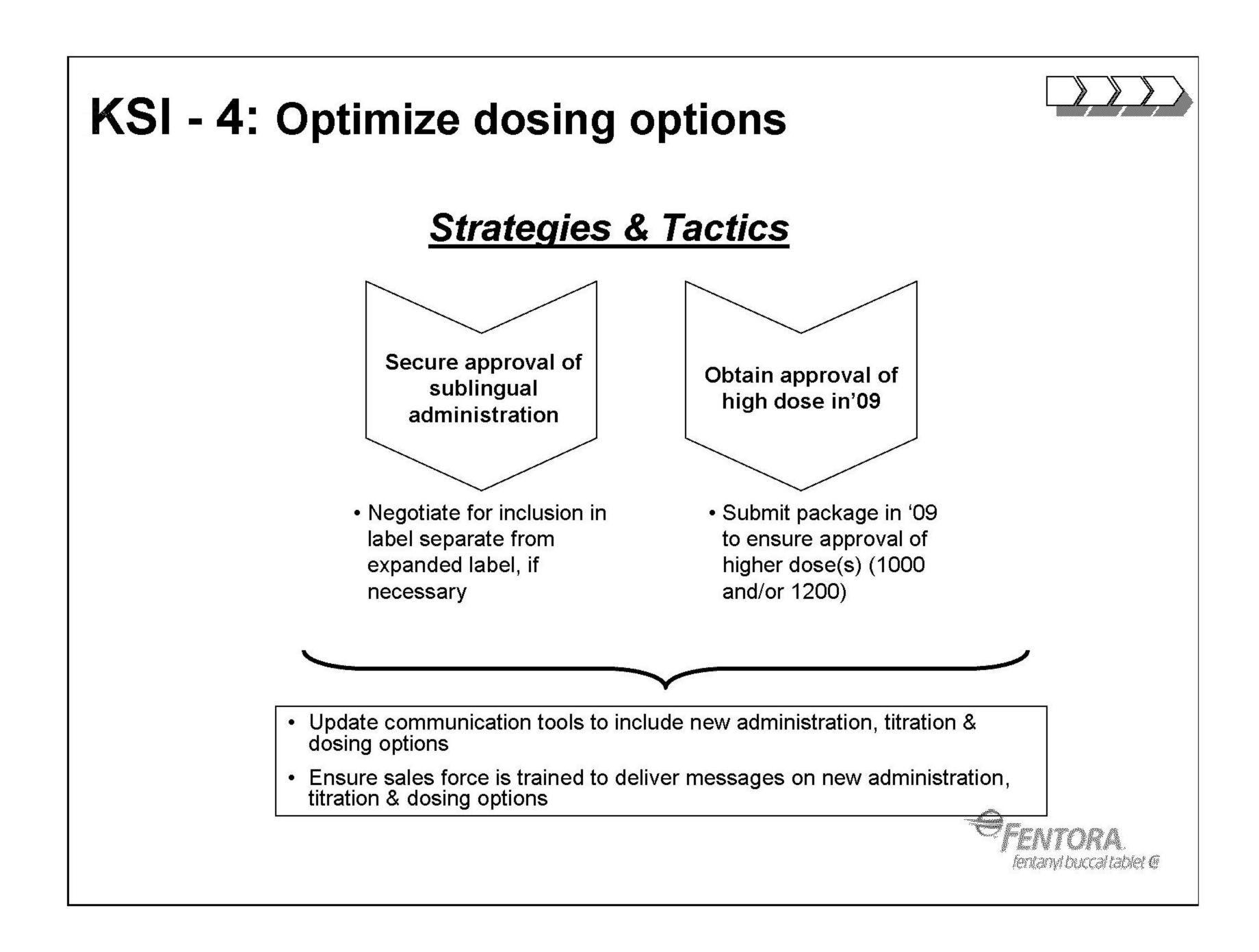
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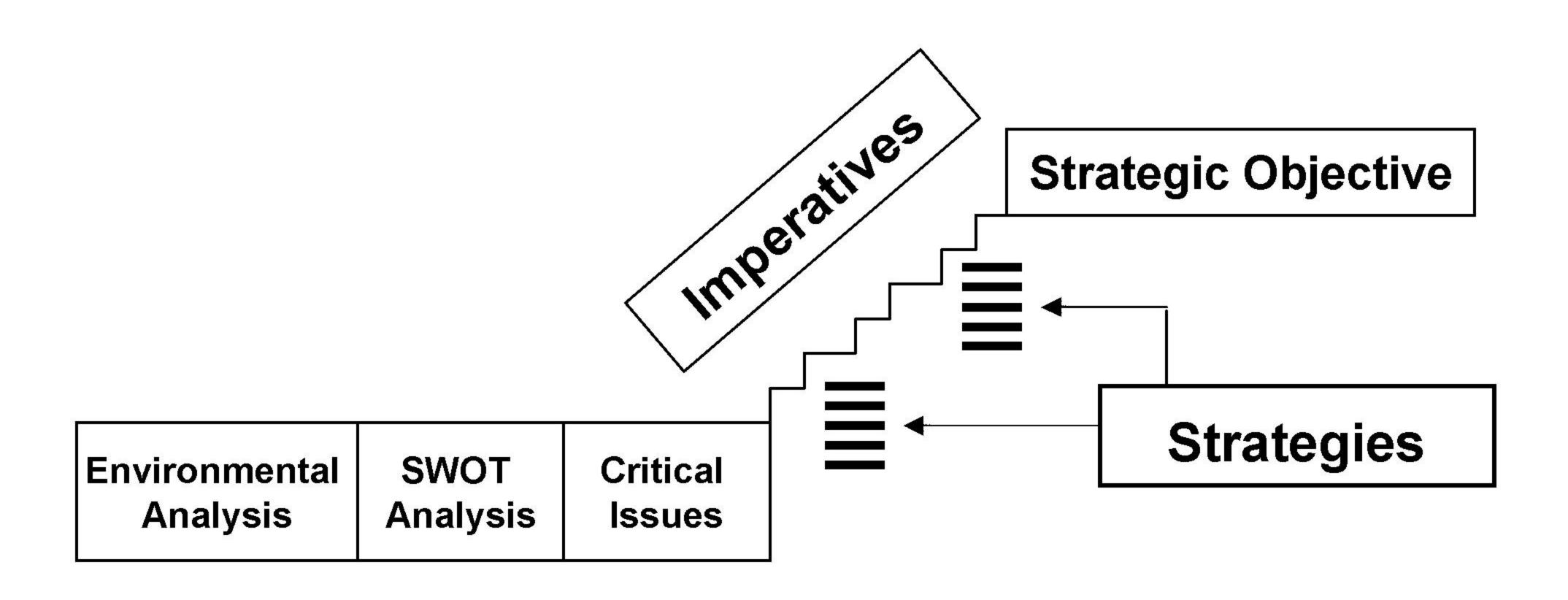


- Key strategic actions to support the "Strategic Imperatives"
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- Key strategic actions to support the "Strategic Imperatives"
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2009 Key Initiatives in Marketing Budget

Total Spend \$10.5M

53%

Ensure appropriate use & Registry - KSI 1

• Registry = \$7.4M

- –Create awareness & understanding of Registry & its value to key stakeholders
 - Two phases of logistics to communicate:
 - "Roll Out" transitions to "Go-Live"
- -Drive enrollment of HCPs, Patients, Pharmacies
- –Reinforce enrollee participation
- Responsible Use of Opioids = \$2.4M
 - -Sales Force tools
 - –Partner w/ patient advocacy & professional organizations on initiatives to support responsible use of opioids
 - –Educate patients & HCPs on safe use of opioids (e.g. managing risk for abuse & diversion, safe storage)
- Market Research = \$750K
 - -HCP/RPh/Pt Surveys, Concept & message testing, CI, Pulse Studies, market surveillance

2009 Key Initiatives in Marketing Budget

Total Spend

\$6.3M

32%

Differentiate from competition

KSI 2,3,4

Differentiate & drive top of mind awareness & usage = \$2.4M

- Create & implement tools/materials for Sales Force to maintain HCP top of mind preference for FENTORA
- Non-personal/targeted media
- Maintain reimbursement access* = \$500K
 - Practice Management Programs
 - Debit Card Program
- Optimize dosing options = \$2.8M
 - Incorporate new label information in all appropriate materials:
 - New REMS/Registry & sublingual administration option
 - High dose & titration
- Market Research = \$600K
 - ATU, secondary reports, CI, Monthly Market Dynamics, National Health & Wellness Survey

* Additional programs/materials/initiatives in HCS Plan

Total Spend 2009 Key Initiatives in Marketing Budget \$2.1M 10% Preparation to optimize market opportunities = \$2M Expanded Develop & incorporate new messaging platform: Label Tools for Sales Force **KSI 2,3** Non-personal/targeted media Maintain reimbursement access* = \$0M Market Research = \$150K Concept & message testing Programs/materials/initiatives in HCS Plan

2009 Marketing Expense Budget

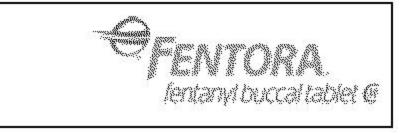


FENTORA Expense Budget

2009 Dollars & Percent-to-total

	646 Forecast	20	09
	2008*	Dollars	Pergent
Total Expense	\$15,175,000	\$20,000,000	
Advertising Promotional Materials	5,775,000	8,850,000	44%
Consultants			
Corporate Contributions	50,000	50,000	0%
Field Driven Speaker Programs	2,700,000	2,300,000	12%
Market Research	1,100,000	1,500,000	8%
Marketing Promotional Programs	0	0	
Medical Education	1,800,000	3,000,000	15%
Meetings, Conf, Congresses, Conv, Exhibits	1,300,000	600,000	3%
Miscellaneous Operating Expense	0	0	
Public Relations	1,000,000	1,100,000	6%
Reprints	250,000	400,000	2%
Risk Management**	0	0	
Samples & Debit Card Program	1,200,000	2,200,000	11%

^{*}Assumes 2009 Expanded Label Launch & SF Expansion



^{**}Assumes Regulatory & GPE will cover REMS & registry program costs

Advertising & Promotion

Total = \$8,650,000

- New campaign development for registry
 - Two label changes to all materials
 - 1. Registry, REMS, sublingual administration
 - 2. High dose
 - Personal (\$5.2M)
 - All sales collateral
 - All REMS related materials
 - Patient education materials
 - Patient Case Studies
 - Non-personal (\$1M)
 - Targeted media (e.g. Triple i tamper proof pads, ePocrates)
 - Journal
 - Direct Mail
 - Web & e-initiatives (\$1.3M)
 - Promotech (\$1.1M)



Promotional Medical Education

- \$3,000,000
 - Regional Summits to support Registry enrollment
 - Update promotional slide decks
 - Web train speakers on new label
 - Advisory Boards (3) for Registry & competition assessment



Samples & Debit Card

- \$2,200,000
 - Vouchers (\$2M)

Voueher Program	1008	20/08	30'H.)
Voucher TRx's	2539	1978	4517
Rep Ordered Vouchers	5810	5950	11760
Redemption Rate	44%	33%	38%

- Debit Cards (\$200K)

www.2003 DebirOard Progran	n
# of Rep Ordered Kits	17/25
# of Rep Ordered Cards	5175
# of Activations	118
# of Redemptions	96
Redemption Rate	2%
# of Patients with 1 use	65
# of Patients with 2 uses	25
# of Patients with 3 uses	8
Avg Redemption Amount	\$36.98



Specialty Pharmacy Tactics

• ???



2009 Contribution Margin



2009 FENTORA Contribution

2009 FENTORA Contribution	Revenue	Expense
Gross Sales Budget	\$155,000,000	
Gross Margin [†]	\$140,900,000	
Marketing		\$20,000,000
Registry		?
Sales*		\$12,800,000
Clinical & Regulatory**		\$3,200,000
Phase IV Studies		2 — 37
Medical Education (SciCom)		\$5,000,000
Publications		\$1,000,000
ISS/IST		\$500,000
Subtotal Expenses		TBD
FENTORA Contribution	TBD	200.00
% of FENTORA Sales	TBD	

*Assumes Sales Force Expansion of PCS to 110 reps and shared costs with Amrix

**Assumes on Clinical Costs/Regulatory & GPE will cover RiskMAP expenses (not included) †Gross Margin = Net sales – COGS

Parking Lot Slides



TEV_FE00037993

KSI - 1: Ensure appropriate use

KSI 1 Total Budget: \$8.4 mm

Strategy: Registry System

Tactic	Timing	Cost	Responsible
Re-launch brand to create awareness and understanding of registry • update all sales force collateral materials with new registry language (personal promo) • create print & web based communication programs to drive awareness with HCPs, patients, and pharmacists (non-personal & e)	1Q	\$2.9m	Brand Team/Palio
Drive Enrollment into Registry • create programs & tools for simple HCP, patient, & pharmacist enrollment (CSPs, SciMedica, spkr training) •Communicate updates to HCPs, patients & pharmacists during transition and Go Live periods	1Q	\$2.8m	Brand Team/Palio
Reinforce enrollee participation •Create ongoing personal and non-personal programs to ensure enrollees continue to use FENTORA appropriately	1Q-4Q	\$700k	Brand Team/Palio



* Summary Implementation Plan:

Use this table to summarize all of the tactical initiatives (as outlined in slides 15-23 of this template) that are planned for 2006 sub-totals by Strategic Imperative. When a tactic applies across multiple imperatives, list it under the strategic imperative it most closely supports.

KSI - 1: Ensure appropriate use

KSI 1 Total Budget: \$8.4 mm

Strategy: Registry System continued

Tactic	Timing	Cost	Responsible
Develop an efficient method to facilitate reimbursement Develop an efficient method to distribute FENTORA (retail vs. specialty) Implement a method to allow for non-retail class of trade to have access	1Q	\$0	Registry Working Team
Market research to ensure registry system logistics & roll out are working	1Q-4Q	\$600k	Market Research
Total Marketing cost for Registry		\$7m	



* Summary Implementation Plan:

Use this table to summarize all of the tactical initiatives (as outlined in slides 15-23 of this template) that are planned for 2006 sub-totals by Strategic Imperative. When a tactic applies across multiple imperatives, list it under the strategic imperative it most closely supports.

		KSI1T	otal Budget: \$8.
egy: Align corporation to leverage registry	T		T
Tactic	Timing	Cost	Responsible
Ensure registry ownership in appropriate functional areas: • Designate & train staff • Monitor objective achievements		\$0	Registry Working Team
Implement an attractive IC plan to support enrollment & prescribing		\$0	Sales Ops
Train sales force & internal key stakeholders on SECURE registry		\$0	Sales Training/ Registry Working Team
PR efforts (web, media & 3 rd party outreach) to support safe use of <i>FENTORA</i> and opioids via —Partnering w/ patient advocacy & professional organizations initiatives —Educating patients & HCPs on understanding & managing risk for abuse & diversion, safe storage		\$675k	Corporate Communications
Total Marketing cost to Leverage		\$675,000	

* Summary Implementation Plan:

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KSI - 1: Ensure appropriate use

KSI 1 Total Budget: \$8.4 mm

Strategy: Effectively communicate the appropriate use of opioids & FENTORA

Tactic	Timing	Cost	Responsible
 Ensure registry ownership in appropriate functional areas: Designate & train staff & Monitor objective achievements Train sales force & internal key stakeholders on SECURE registry 		\$0	Sales Training/ Registry Working Team
Implement an attractive IC plan to support enrollment & prescribing		\$0	Sales Ops
Provide sales force with tools to continue to educate on appropriate patient selection and safe use of opioids and <i>FENTORA</i> (AAD CSPs)		\$700k	Brand Team
Total Marketing cost ensure safe use of opioids & FENTORA		\$700,000	



KSI 2: Total Budget: \$8.4M

Strategy: Increase BTP awareness & understanding

Tactic	Timing	Cost	Responsible
Partner w/ key associations on educational & guideline initiatives	1Q/4Q	\$100K	PR
Continue to support ESP	1Q/4Q	\$0	SciCom

Strategy: Maintain customer loyalty

Tactic	Timing	Cost	Responsible
Increase call reach & frequency w/ expanded PCS Sales Force (110) through IC plan	1Q/4Q	\$0	Sales/Sales Ops
Vouchers	1Q/4Q	\$900K	Brand Team
Implement Publication Plan	1Q/4Q	\$0	SciCom
Train PCS on how to address new competition	1Q	\$ 0	Sales Ttraining
Nurse Advisory Board to obtain insights on educational/ other unmet needs	2Q	\$100K	PR

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KSI 2: Total Budget: \$8.4M

Strategy: Optimize all communication channels

Tactic	Timing	Cost	Responsible
Create & implement tools & materials to address competition	1Q/4Q	\$800K	Brand Team/Palio
Create & implement tools/materials for Sales Force to maintain HCP top of mind preference for FENTORA	3Q/4Q	\$285K	Brand Team
Reprints: Fees & production	1Q/4Q	\$325K	Brand Team
Targeted media: ePocrates , Catalina Newsletter, PDR, PDR Pain Prescribing Guide	1Q/4Q	\$850K	Brand Team
Website initiatives: maintain site & update with new content to drive HCP & patient hits	1Q/4Q	\$350K	Brand Team
eDetails	1Q/2Q	\$215K	Brand Team
Journal advertising in select journals, targeted reach	1Q/4Q	\$600	Brand team
Conventions: Booth presence to distribute educational product information at key Pain professional meeting (space, fees, shipping, other logistics		\$600	Brand Team

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KSI 2: Total Budget: \$8.4M

Strategy: Optimize all communication channels

Tactic	Timing	Cost	Responsible
PR: media outreach & monitoring on new data releases	1Q/4Q	\$100 K	PR
PR: Webinar & collateral material to educate HCPs & patients	3Q/4Q	\$300K	Brand Team
Market Research: ATU, CI, secondary reports, monthly dynamics, National Health & Wellness Survey	1Q/4Q	\$300.5K	Market Research



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KSI 2: Total Budget: \$8.4M

Strategy: Optimize all communication channels: preparation effective for expanded label

Tactic	Timing	Cost	Responsible
Create new message campaign for expanded label launch; incorporate concept into Sales Force & non-personal collateral materials	3Q/4Q	\$1.1M	Brand Team/Palio
Production cost of tools/materials as appropriate	/4Q	\$600K	Brand Team
CSP: • Content development • Speaker training		\$600K	Brand Team/CCX
Market Research: Test concepts & messaging	2Q/4Q	\$125K	Market Research
PR: Manage regulatory milestones		\$185K	PR



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KSI 2: Total Budget: \$8.4M

Strategy: Formally establish ROO class

Tactic	Timing	Cost	Responsible
Support development & execution chronic pain/BTP treatment guidelines	1Q/4Q	\$O	Med Affairs
Appropriately leverage new clinical data when available	1Q/4Q	\$ O	Mkting/Gov Affairs
Lobby USP for formal creation of ROO class	3Q	\$ 0	Gov Affairs



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KSI - 3: Increase access to reimbursement

KSI 3: Total Budget: \$550K

Strategy: Facilitate reimbursement process

Tactic	Timing	Cost	Responsible
COVANCE	1Q/4Q	\$0	HCS
Practice Manager Programs	1Q/4Q	\$175K	Brand team
Formulary Kit	2Q	\$0	HCS
Debit Card Program	1Q/4Q	\$300K	Brand team

Strategy: Secure optimal Formulary status

Tactic	Timing	Cost	Responsible
Conduct PE study; utilize data to support utilization	1Q/4Q	\$0	HCS/Clinical/Med Affairs/SciCom
Update AMCP Dossier to include PE & new clinical data	1Q/4Q	\$0	HCS/Med Affairs
Support independent third party development & execution chronic pain/BTP treatment guidelines; disseminate appropriately	1Q/4Q	\$75K	Med Affairs/HCS/Brand Team
Develop & convey BOI for BTP	1Q/4Q	\$0	HCS/Med Affairs

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KSI - 3: Increase access to reimbursement

KSI 3: Total Budget: \$550K

Strategy: Selectively secure MCO contracts

Tactic	Timing	Cost	Responsible
Create infrastructure to support contracting	1Q	\$0	HCS
Create process to support contracting	1Q	\$0	HCS
Train NAMs: •Negotiation skills •Cephalon contracting process	1Q/2Q	\$0	HCS



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KSI - 4: Expand administration, titration & dosing options

KSI-4: Total Budget: \$1.5M

Strategy: Revise the label to include sublingual administration and high dose(s)

Tactic	Timing	Cost	Responsible
Negotiate label language describing optional sublingual administration	1Q	\$0	Regulatory
Develop, submit & obtain approval of supplement for high dose(s)	1Q	\$0	Regulatory/Clinical
Update Sales Force communication tools to include new administration, titration & dosing options (2x pending approvals)	2Q	\$500K	Brand Team & Palio
Non-personal tactics to communicate new sublingual administration option (creation, production, distribution, program fees)	2Q	\$325K	Brand Team & Palio



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KSI - 4: Expand administration, titration & dosing options

KSI-4: Total Budget: \$1.5M

Strategy: Revise the label to include sublingual administration and high dose(s)

Tactic	Timing	Cost	Responsible
Non-personal tactics to communicate new high dose option options (creation, production, distribution, program fees)	3Q	\$325K	Brand Team & Palio
Update CSP deck & web-train the speakers on new dosing, titration & administration options (2x pending approvals)	2Q & 3Q	\$300K	Brand Team & CCX
Develop training materials/tools & train sales force to deliver messages on new administration, titration & dosing options	2Q	\$0	Sales Training



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